UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,414	06/30/2003	David P. Holden	ABIOS.021A	1954

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EXAMINER
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ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/611,414	HOLDEN ET AL.
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *14 February 2008*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15,17,19-21,84 and 85* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-15, 17, 19-21, and 84-85* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 2/14/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 2/14/2008, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 1-15, 17, 19-21, and 83-84 are the current claims hereby under examination.

Claim Rejections - 35 USC § 101

Response to Arguments:

Applicant's arguments, filed 2/14/2008, with respect to the rejection of claims under 35 USC 101 have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112

Response to Arguments:

Applicant's arguments, filed 2/14/2008, with respect to the rejections of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejections have been withdrawn.

Claim Rejections - 35 USC § 102

Response to Arguments:

Applicant's arguments, filed 2/14/2008, with respect to the rejection of claims under 35 USC 102 have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

The following rejection is being newly applied and has been necessitated by amendment:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-8, 10-12, 19-21, and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glanowski et al. (US P/N 7,272,506) in view of Liu et al. (US P/N 6,920,398).

The claims are directed to a method for allelic classification, the method comprising:

I) acquiring intensity information for each of a plurality of samples wherein the intensity information for each sample of the plurality of samples comprises a first intensity component representing the detected emission of a first probe specific for a first allele of a gene and a second intensity component representing the detected emission of a second probe specific for a second allele of the gene;

II) forming a plurality of data sets from the intensity information, such that each data set comprises the first intensity component and the second intensity component from a respective one of the plurality of samples;

III) grouping the plurality of data sets into one or more data clusters by evaluating at least the relationship between the first intensity component and the second intensity component for each of the plurality of samples wherein each data cluster represents a discrete allelic classification comprising one of, a homozygous allelic combination comprising the first allele alone, a homozygous allelic combination comprising the second allele alone, or a heterozygous allelic combination comprising both the first allele and the second allele;

IV) defining bounds for each of the one or more data clusters;

V) generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within the bounds of a particular data cluster of the one or more data clusters based upon the intensity information of the selected sample;

VI) applying the likelihood model to the intensity information of each of the plurality of samples to identify the allelic classification of each sample of the plurality of samples; and

VII) outputting the allelic classification of each of the plurality of samples to at least one of a user and a display.

Glanowski et al. teach at the abstract, a method of allele classification. Glanowski et al. teach at col. 1, lines 55-67, col. 2 lines 1-6, and col. 3, lines 16-20 wherein the method involves two probes for determining homozygosity for

either allele or heterozygosity for the two alleles, which reads on acquiring intensity information for each of a plurality of samples wherein the intensity information for each sample of the plurality of samples comprises a first intensity component representing the detected emission of a first probe specific for a first allele of a gene and a second intensity component representing the detected emission of a second probe specific for a second allele of the gene. Glanowski et al. at col. 2, lines 6-55 teach using a plurality of samples and clustering the data sets in order to classify a genotype, which reads on steps II-IV of the method claim 1.

Glanowski et al. does not explicity teach generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within the bounds of a particular data cluster of the one or more data clusters based upon the intensity information of the selected sample.

However, Glanowski et al. does teach classifying the samples based on the clustering data. Therefore, it is implied that the step of classifying samples, which is based on the intensity information from the samples combined with the clustered data of intensity information from a plurality of samples, reads on using a likelihood model that performs step V of the instant claim. This is because the classification is itself a prediction based on probability as taught at col. 4, lines 20-25. Furthermore, this step of classifying also implies the application of a likelihood model because it is used to classify the intensity data of each sample and predict outcomes of unknown samples.

Liu et al. at col. teaches a method of classifying alleles of clustered data, i.e. sets of data clustered into subsets, using a likelihood function at col. 3, lines 25-30, col. 7, lines 29-31 and at col. 8, lines 1-2.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply the likelihood model taught by Liu et al. to the sample sets obtained by Glanowski et al. to classify alleles. This is because using various statistical methods for data analysis is within the ordinary skill of the artisan. Therefore, when looking to apply a statistical method for data analysis one of ordinary skill in the art would turn to available statistical methods, such as the likelihood model taught by Liu et al., which can be used for classifying alleles as taught by Glanowski et al. and the results would have been predictable. Furthermore the use of different statistical methods for data analysis, such as in the instant case, is the use of obvious variations of the same method to arrive at the result. Therefore, one of ordinary skill in the art would have been capable of applying this known technique to a known data analysis that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

Glanowski et al. further teach at col. 3, lines 28-30 outputting the results to a user.

With respect to claim 2, Liu et al. teach a model-fit probability to the classification of a haplotype at col. 4, lines 7-17.

Liu et al. does not specifically teach using an in-class or a posteriori probability as in claims 3 and 4.

However, the use of varying probability functions for data analysis is considered a known technique that is applicable to the data for analysis. . Furthermore the use of different statistical methods for data analysis, such as in the instant case, is the use of obvious variations of the same method to arrive at the result. Therefore, one of ordinary skill in the art would have been capable of applying this known technique to a known data analysis that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

With respect to claim 13, Liu et al. teaches the use of controls in the datasets wherein the taught algorithms were applied, which involve iteratively scaling and fitting data.

With respect to claims 14, 15, and 17 Liu et al. teach using an iterative method for refining a likelihood model at col. 7, lines 29-31 and col. 8, lines 1-2.

With respect to claim 5, Glanowski et al. teach forming three distinct clusters at col. 4, lines 29-42.

With respect to claims 6-8, Glanowski et al. teach the clustering of three categories at col. 3, lines 16-20 and col. 5, lines 25-31.

With respect to claims 9-10, Glanowski et al. teach at col. 1, lines 30-48 the classification of SNPs, which include mutations.

With respect to claim 11, Glanowski et al. teach at col. 3, lines 28-41 allelic classification.

With respect to claim 12, Glanowski et al. teach at Fig. 4, a plot of normalized sample fluorescent data.

With respect to claim 19, Glanowski et al. at col. 1, lines 55-60, teach about an amplification protocol used for acquiring intensity information.

With respect to claim 20, it is implied that the use of an amplification protocol as discussed at col. 1, lines 55-60 comprises a Taqman or SNPlex protocol or an unobvious variation.

With respect to claim 21, it is further implied that fluorescence detection as taught by Glanowski et al. at col. 1, lines 60-67 use an array-based detection protocol.

With respect to claims 84-85, Glanowski et al. teach the plots at figures 1-3.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631